NDA 18-893/S-013

Abbott Laboratories
Attention: Thomas F. Willer, Ph.D.
Assistant Director, Regulatory Affairs
200 Abbott Park Road, D-389, AP30
Abbott Park, IL 60064-3537

Dear Dr. Willer:

Please refer to your supplemental new drug application dated July 17, 1998, received July 21, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Sodium Acetate Injection in Plastic Vials.

This supplemental new drug application provides for a labeling revision in response to the final rule, effective August 27, 1998, entitled *"Specific Requirements on Content and Format of Labeling for Human Drugs: Addition of Geriatric Use Subsection in the Labeling."* More specifically, the proposed labeling revision is as follows:

To the **PRECAUTIONS** section of the package insert, the following paragraph has been added:

> **Geriatric Use:** An evaluation of current literature revealed no clinical experience identifying differences in response between elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
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> Sodium (and potassium) ions are known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.